REMARKS

Claims 21-34 have been amended to add the term "endogenous" in reference to the glycoproteins, glycosaminoglycans, and proteoglycans that are naturally occurring within the graft prosthesis. Support for these claim amendments is found on page 14, lines 1-2 of the original application as filed.

The Examiner has rejected claims 1-6, 11, 14, 21, and 22 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,993,844 (the '844 patent). The Examiner indicates that the '844 patent anticipates claims 1-6, 11, 14, 21, and 22 because the '844 patent describes graft constructs that are endotoxin-free and, according to the Examiner, a graft construct that is "endotoxin-free" is within the ranges claimed in the present application. Applicants respectfully traverse the Examiner's rejection. Claims 1-6, 11, 14, 21, and 22 are not anticipated by the '844 patent.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). The '844 patent describes a graft prosthesis from which non-collagenous material has been deliberately removed (see abstract and column 4, lines 1-3 of the '844 patent). In fact, the '844 patent states the following (see abstract).

> The invention is directed to collagenous tissues which have been treated to remove non-collagenous components such as cells, cellular debris, and other extracellular matrix components, such as proteoglycans and glycosaminoglycans, normally found in native tissues.

Thus, the tissue matrices described in the '844 patent are rendered substantially free of glycoproteins, glycosaminoglycans, proteoglycans, and non-collagenous proteins by treating the tissue with alkali, chelating agents, acids, and salts (see abstract). Moreover, it is stated in the '844 patent that the method described therein removes non-collagenous components resulting in a tissue matrix that is "substantially free of glycoproteins, glycosaminoglycans, proteoglycans,

lipids, non-collagenous proteins, and nucleic acids such as DNA and RNA" (see abstract and column 4, lines 1-3 of the '844 patent).

The graft constructs claimed in claims 1-6, 11, 14, 21, and 22 of the present application comprise a "collagen-based matrix structure." As stated on page 14, lines 1-2 of the present application, the matrices in accordance with the present invention contain one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors. These components are naturally-occurring and are not deliberately removed, as described in the '844 patent, so the presence of glycoproteins, glycosaminoglycans, and proteoglycans is not an exemplification as the Examiner suggests. In this regard, the graft constructs in accordance with the present invention contain one or more naturally occurring components including glycoproteins, glycosaminoglycans, and proteoglycans and/or growth factors, and cannot be anticipated by the '844 patent which describes tissue matrices from which these naturally occurring components have been deliberately removed.

In regard to claims 21 and 22, the Examiner indicates that the '844 patent discloses that glycoproteins, glycosaminoglycans, and proteoglycans can be added back into the tissue matrices described in the '844 patent. However, components added back to the tissue matrix are ***exogenously added*** components. Applicants have amended claims 21-34 to require that the glycoproteins, glycosaminoglycans, and proteoglycans specified in the claims are ***endogenous*** glycoproteins, glycosaminoglycans, and proteoglycans. Thus, the '844 patent cannot anticipate claims 21 and 22. Furthermore, the '844 patent does not anticipate claims 1-6, 11, and 14 based on the arguments discussed above. Withdrawal of the rejection of claims 1-6, 11, 14, 21, and 22 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent is respectfully requested.

Moreover, with regard to the meaning of "EU/g," the Examiner previously contended that U.S. Provisional Application Serial No. 60/024,542 (the '542 application) did not

contain support for the phrase "endotoxin units per gram," found in claim 3, because the '542 application did not set forth the meaning of "EU/g." According to the Examiner, this phrase could not be assumed to mean "endotoxin units per gram." However, the Examiner has now conceded that "EU/g" is well-known in the art to mean "endotoxin units per gram" (see last paragraph on page 6 of the September 10, 2007 office action).

The '542 application, filed on August 23, 1996, recites less than "5 EU/g" on, for example, page 7, lines 16-17. Consequently, the Examiner should not be rejecting claim 3 over the '844 patent because there is support for the phrase "less than 5 endotoxin units per gram" in the '542 application. The effective filing date of claim 3 is August 23, 1996 which is prior to the filing date of the '844 patent. Accordingly, Applicants further request withdrawal of the rejection of claim 3 under 35 U.S.C. § 102(e) because this claim is not anticipated by the '844 patent. The '844 patent is not proper prior art to claim 3.

The Examiner has rejected claims 7-10, 16-20, and 23-31 under 35 U.S.C. § 102(e) as allegedly being anticipated by the '844 patent or, in the alternative, as being obvious under 35 U.S.C. § 103(a) over the '844 patent. The arguments discussed above in the second through the fourth paragraphs of this section of the response, apply with equal force to this rejection. Moreover, the subject matter of claims 9, 10, and 16-20 is not disclosed or suggested by the '844 patent. The '844 patent provides no suggestion of cleaning the graft prosthesis prior to delamination (see claims 9, 10, and 16-20).

The Examiner concludes that claims 7-10, 16-20, and 23-31 are product-by-process claims. According to MPEP § 2113, "[t]he structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive

structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)." MPEP § 2113.

Claims 7-10, 16-20, and 23-31 are all directed to purified matrices. If claims 7-10, 16-20, and 23-31 are product-by-process claims, as indicated by the Examiner, the process steps would be expected to impart distinctive structural characteristics to the final product. Each of these claims is directed to a purified matrix. The matrix composition (*i.e.,* including removal of contaminating nucleic acids, infectious agents, and endotoxins) imparts distinctive characteristics to the final purified product so the product is defined by the process steps, if these claims are product-by-process claims as the Examiner suggests.

Moreover, if claims 23-31 are product-by-process claims, the product of claims 23-31 is clearly a different product than the product of the '844 patent. As discussed above, the components added back to the tissue matrix of the '844 patent are exogenously added components. Applicants have amended claims 23-31 to require that the glycoproteins, glycosaminoglycans, and proteoglycans specified in the claims are "endogenous" glycoproteins, glycosaminoglycans, and proteoglycans. Thus, the '844 patent cannot anticipate or render obvious claims 23-31 because the product of claims 23-31 is clearly a different product than the product of the '844 patent. Withdrawal of the rejection of claims 7-10, 16-20, and 23-31 under 35 U.S.C. § 102(e) as being anticipated by the '844 patent, or under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested, based on the foregoing arguments.

The Examiner has rejected claims 12, 13, 32, and 33 under 35 U.S.C. § 103(a) as being obvious over the '844 patent. The Examiner has also rejected claims 15 and 34 under 35 U.S.C. § 103(a) as being obvious over the '844 patent in combination with Braun. The arguments discussed above, in the second through the fourth paragraphs of this section of the response, apply with equal force to this rejection in the context of obviousness. Moreover, the graft constructs of claims 32-33 and 34 cannot be obvious over the tissue matrices described in

the '844 patent. As discussed, the components added back to the tissue matrix described in the '844 patent are ***exogenous*** components. Applicants have amended claims 32-33 and 34 to require that the glycoproteins, glycosaminoglycans, and proteoglycans specified in the claims are ***endogenous*** glycoproteins, glycosaminoglycans, and proteoglycans. Endogenous glycoproteins, glycosaminoglycans, and proteoglycans are deliberately removed from the tissue matrices described in the '844 patent. Thus, claims 32-33 and 34 cannot be obvious over the '844 patent. Withdrawal of the rejection of claims 12, 13, and 32-33 under 35 U.S.C. § 103(a) as being obvious over the '844 patent is respectfully requested. Withdrawal of the rejection of claims 15 and 34 under 35 U.S.C. § 103(a) as being obvious over the '844 patent in combination with Braun is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. Applicants respectfully request issuance of an action indicating that the claims are allowable, and issuance of a declaration of interference.

Respectfully submitted,

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